

AMENDMENTS TO THE CLAIMS

Claims 1-41 (Cancelled)

42. (Previously presented) A method of hormone replacement therapy, comprising administering to a woman in need thereof an effective amount of estrogen in combination with an effective amount of a progestin, and an amount of antiprogestin effective to ameliorate uterine bleeding problems associated with hormone replacement therapy.

43. (Previously Presented) A method of claim 42, wherein the antiprogestin is administered periodically.

44. (Previously Presented) A method of claim 42, wherein the antiprogestin is administered continuously.

Claims 45 to 55. (Cancelled)

56. (Previously presented) A method of hormone replacement therapy comprising administering to a woman in need thereof an effective amount of estrogen, with progestin administration, and an amount of antiprogestin effective to inhibit breakthrough bleeding.

57. (Previously Presented) A method of claim 56 wherein the antiprogestin is administered periodically.

58. (Previously Presented) A method of claim 56, wherein the antiprogestin is administered continuously.
59. (Previously Presented) A method of claim 57, wherein the estrogen is administered continuously.
60. (Previously Presented) A method of claim 58, wherein the estrogen is administered continuously.
61. (Previously presented) A method of hormone replacement therapy comprising administering to a woman in need thereof an effective amount of estrogen, with progestin administration, and an amount of antiprogestin equivalent to an oral dose of about 1.0 to about 10 mg/kg of weight of the woman.
62. (Previously Presented) A method of claim 61, wherein the antiprogestin is administered periodically.
63. (Previously Presented) A method of claim 61, wherein the antiprogestin is administered continuously.
64. (Previously Presented) A method of claim 62, wherein the estrogen is administered continuously.
65. (Previously Presented) A method of claim 63, wherein the estrogen is administered continuously.

66. (Previously Presented) A method of claim 61, wherein the dose is 50-500 mg.

67. (Previously presented) A method of hormone replacement therapy comprising administering to a woman in need thereof an effective amount of estrogen, with progestin administration, and an antimitotically effective amount of antiprogestin.

68. (Previously Presented) A method of claim 67 wherein the antiprogestin is administered periodically.

69. (Previously Presented) A method of claim 67, wherein the antiprogestin is administered continuously.

70. (Previously Presented) A method of claim 68, wherein the estrogen is administered continuously.

71. (Previously Presented) A method of claim 69, wherein the estrogen is administered continuously.

72. (Previously presented) A method of hormone replacement therapy comprising administering to a woman in need thereof an effective amount of estrogen, with progestin administration, and an amount of antiprogestin effective to inhibit endometrial growth.

73. (Previously Presented) A method of claim 72, wherein the antiprogestin is administered periodically.

74. (Previously Presented) A method of claim 72, wherein the antiprogestin is administered continuously.

75. (Previously Presented) A method of claim 73, wherein the estrogen is administered continuously.

76. (Previously Presented) A method of claim 74, wherein the estrogen is administered continuously.

Claims 77-81 (Cancelled)

82. (Previously presented) A method of avoiding the bleeding problems associated with administering to a female mammal dosage amounts of an estrogen low enough to create incidents of breakthrough bleeding and withdrawal amenorrhea during hormone replacement therapy, which comprises (a) administering the estrogen daily without interruption and (b) administering progestin and (c) periodically, at intervals of at least about a month, administering to the female an amount of an antiprogestin effective to reduce or eliminate breakthrough bleeding and, optionally, to induce sloughing of accumulated endometrial tissue and thereby induce menses.

83. (Previously Presented) A method of claim 82, wherein the estrogen and the daily dose thereof is ethinyl estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

Claims 84 to 85. (Canceled)

86. (Currently amended) A method of claim ~~85~~ 82, wherein the amounts of the estrogen and the progestin which are administered are effective to suppress endometrial proliferation.

87. (Previously presented) A method of claim 82, wherein the administration of the progestin is continued uninterrupted throughout the cycle.

88. (Previously presented) A method of claim 82, wherein the administration of progestin is interrupted proximate the day of antiprogestin administration.

89. (Previously presented) A method of claim 82, wherein the antiprogestin is administered about monthly.

90. (Previously presented) A method of claim 82, wherein the antiprogestin is administered orally.

91. (Previously presented) A method of claim 82, wherein the antiprogestin is onapristone or mifepristone.

92. (Previously presented) The method of claim 82, wherein the progestin is gestodene or norethindrone acetate.

93. (Currently amended) The method of claim 82, wherein the estrogen, the progestin and the antiprogestin are administered orally; wherein the administration of the progestin and the estrogen is continued uninterrupted throughout the cycle and wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

94. (Previously presented) The method of claim 82, wherein the female is a para- or postmenopausal woman.

95. (Previously Presented) The method of claim 94, wherein the estrogen is administered in combination with a progestin.

96. (Previously Presented) The method of claim 95, wherein the administration of the progestin is continued uninterrupted during the period of antiprogestin administration.

97. (Previously Presented) The method of claim 95, wherein the administration of the progestin is interrupted proximate the period of antiprogestin administration.

98. (Previously Presented) The method of claim 94, wherein the antiprogestin is onapristone or mifepristone.

99. (Previously Presented) The method of claim 94, wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15

mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

100. (Previously Presented) The method of claim 95, wherein the antiprogestin is onapristone or mifepristone; and wherein the progestin is gestodene or norethindrone acetate.

101. (Previously Presented) The method of claim 95, wherein the estrogen, progestin and antiprogestin are administered orally; wherein the antiprogestin is administered at longer than one month intervals; wherein the administration of the progestin is continued uninterrupted during the period of antiprogestin administration; and wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

102. (Previously presented) A kit containing at least about 20 estrogen and progestin-containing tablets, which collectively contain amounts thereof which are too low to avoid breakthrough bleeding incidents where administration of the tablets is interrupted for a week during each monthly cycle to induce menses; and containing a tablet, arranged in the kit so as to be taken after at least 20 of the estrogen and progestin-containing tablets have been taken, which contains an amount of antiprogestin effective to induce menses.

103. (Previously Presented) A kit according to claim 102, containing 28 of the estrogen and progestin-containing tablets, arranged to be taken sequentially with the antiprogestin-containing tablet positioned as the 20th or later tablet in the sequence.

104. (Previously Presented) A kit according to claim 102, wherein the antiprogestin is onapristone or mifepristone; and wherein the progestin is gestodene or norethindrone acetate.

105. (Previously Presented) A kit according to claim 102, wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

Claims 106-107 (Cancelled)

108. (Previously presented) A method of avoiding the bleeding problems associated with administering to a female mammal dosage amounts of an estrogen low enough to create incidents of breakthrough bleeding and withdrawal amenorrhea during hormone replacement therapy, which comprises (a) administering the estrogen daily without interruption and (b) administering progestin and (c) periodically, at intervals of at least about a month, administering to the female an amount of an antiprogestin effective to reduce or eliminate breakthrough bleeding and, optionally, to induce sloughing of accumulated endometrial tissue whereby menses is induced.

Claim 109. (Cancelled)

110. (Previously presented) The method of claim 108, wherein the estrogen is administered in combination with a progestin in an amount effect to suppress endometrial proliferation.

Claim 111. (Cancelled)

112. (Previously presented) The method of claim 108, wherein the administration of the progestin and estrogen is interrupted proximate the day of antiprogestin administration.

113. (Previously Presented) The method of claim 108, wherein the antiprogestin is administered about monthly.

114. (Previously presented) The method of claim 108, wherein the antiprogestin is administered orally.

115. (Previously presented) The method of claim 108, wherein the antiprogestin is mifepristone.

116. (Previously presented) The method of claim 108, wherein the estrogen is ethynodiol diacetate.

117. (Previously presented) The method of claim 108, wherein the progestin is norethindrone acetate.

118. (Cancelled)

119. (Previously presented) The method of claim 108, wherein the female is a para- or postmenopausal woman.

120. (Previously Presented) The method of claim 119, wherein the antiprogestin is administered at longer than monthly intervals.

121. (Previously presented) The method of claim 108, wherein the administration of the progestin and estrogen is continued uninterrupted throughout the cycle, including during menses.

122. (Previously presented) The method of claim 121, wherein the administration of the progestin is interrupted proximate the day of the antiprogestin administration.

123. (Previously Presented) The method of claim 119, wherein the antiprogestin is administered orally.

124. (Previously Presented) The method of claim 119, wherein the antiprogestin is mifepristone.

125. (Previously Presented) The method of claim 119, wherein the estrogen is ethinyl estradiol or estradiol.

126. (Previously presented) The method of claim 108, wherein the progestin is norethindrone acetate.

127. (Previously presented) The method of claim 108, wherein the female mammal is a para- or postmenopausal woman, wherein the antiprogestin is administered orally at longer than one month intervals and the administration of the progestin and estrogen is continued uninterrupted during the period of antiprogestin administration.

128. (Currently amended) A kit containing estrogen and progestin-containing tablets, which collectively, when 21 thereof are taken on successive days by a female human, being contain amounts thereof which are too low to avoid breakthrough bleeding incidents where administration of the tablets is interrupted for a week during each monthly cycle to induce menses; and containing a tablet, arranged in a kit so as to be taken after at least 20 of the estrogen and progestin-containing tablets have been taken, which contains an amount of an antiprogestin effective to induce menses.

129. (Previously Presented) A kit according to claim 128, containing 28 of the estrogen and progestin containing tablets, arranged to be taken sequentially with the anti-progestin containing tablet positioned as the 20th or later tablet in the sequence.

130. (Previously Presented) A kit according to claim 128, wherein the estrogen is ethinyl estradiol, the progestin is norethindrone acetate and the antiprogestin is mifepristone.

131. (Previously Presented) A kit according to claim 128, wherein the estrogen is ethinyl estradiol, the progestin is gestodene and the antiprogestin is onapristone.

132. (Previously presented) A pharmaceutical composition in solid oral unit dosage form comprising amounts of an estrogen and of a progestin equivalent to 5 mcg. to 35 mcg. of ethinyl estradiol and 0.5 mg. to 1.5 mg. of norethindiol acetate, respectfully, and an amount of an antiprogestin effective to induce menses in a female human being who has ingested daily for at least 20 days corresponding amounts of the estrogen and progestin.

133. (Previously presented) A pharmaceutical composition according to claim 132, containing 0.5 to 35 mcg. ethinyl estradiol, 0.5 to 35 mg norethindrone acetate and 50 to 500 mg. of mifepristone.

134. (Previously presented) A pharmaceutical composition according to claim 132, containing 0.5 to 35 mcg. ethinyl estradiol, 10 to 15 mcg. gestodene and 50 to 500 mg. of onapristone.